Remarks

In view of the above amendments and the following remarks, reconsideration of the grounds of rejection set forth in the outstanding office action is respectfully requested.

Claims 1, 9, 12, and 13 have been amended, and claims 2, 6-8, 10, 11, and 14-31 have been cancelled without prejudice. Claim 1 has been amended to recite the limitations presented in original claims 2 and 8. Claim 1 has also been amended to clarify that the female patient (being treated) has a pathological condition of the uterus as recited, and that the FP receptor antagonist is administered to the female patient under conditions effective to treat the pathological conditions. Therefore, no new matter has been introduced.

Claims 1, 3-5, 9, 12, and 13 remain pending.

The rejection of claims 14-18 under 35 U.S.C. § 101 is rendered moot by the cancellation of these claims. This rejection should be withdrawn.

The rejection of claims 1-8, 12, and 13 under 35 U.S.C. § 112, first paragraph, for failure to comply with the written description requirement is rendered moot with respect to cancelled claims 6-8 and is otherwise respectfully traversed.

The U.S. Patent and Trademark Office ("PTO") has taken the position on page 4 of the office action that the specification provides descriptive support for only two agents that prevent PGF2α having its effect on the FP receptor, namely AL-3138 and AL-8810. These compounds are FP receptor antagonists. The PTO appears to have overlooked the disclosure on page 7, line 21, to page 10, line 4, which provides extensive examples of FP receptor (i.e., $PGF_{2\alpha}$ receptor) antagonists. These include the 19 peptides listed in Table 1, the class of 11β-fluoro, 15β-hydroxy $PGF_{2\alpha}$ analogs described in U.S. Patent No. 6,441,033 to Sharif et al. ("Sharif"), and the 8 other compounds identified on pages 9-10. Furthermore, U.S. Patent No. 6,300,312 B1 Chemtob et al. ("Chemtob") and U.S. Patent No. 6,492,417 to Sharif et al. describe, respectively, several peptides and a class of 11-deoxy-16-fluoro-$PFG_{2\alpha}$ analogs as FP receptor antagonists.

Thus, there is plainly an adequate written description and disclosure of FP receptor antagonists. The use of these and other FP receptor antagonists in the manner claimed is sufficiently described in the present application to demonstrate that applicants

were in possession of the claimed invention. For this reason, the rejection of claims 1-8, 12, and 13 for failure to comply with the written description requirement should be withdrawn.

The rejection of claims 1-9, 12, and 13 under 35 U.S.C. § 112, first paragraph, as lacking enablement is respectfully traversed in view of the above amendments.

The PTO has cited two bases of rejection: (i) The claims are not enabled for prevention, and (ii) the application lacks data to enable the subject matter of claims 2-5. The first basis of rejection is rendered moot by the above claim amendments. With regard to the second basis of rejection, applicants respectfully disagree for the reasons discussed below.

Claim 1 has been amended to recite that the pathological condition of the uterus is associated with abnormal growth of cells of the myometrium or endometrium. The present application provides data to support such treatment methods. Example 1 describes studies which show that the FP ($PGF_{2\alpha}$) receptor is expressed in human endometrium and endometrial adenocarcinoma. More particularly, a significantly increased expression of FP receptor mRNA was observed in mid- to late-proliferative tissue that was increased further in endometrial adenocarcinomas (*see* page 24, lines 17 to 22). FP receptor expression in human endometrium demonstrated a distinctive localization pattern across the cycle, with the FP receptor being localized to glandular epithelial cells in only mid- and late-proliferative stages of the menstrual cycle (page 31, lines 9 to 12), and in uterine adenocarcinoma biopsies, FP receptor expression was localized to epithelial cells and was observed in all differentiation types with no discernible change in pattern between poor, moderately or well differentiated samples (*see* page 31, lines 13 to 17).

These results support the view that expression of the FP receptor is important in pathological conditions of the uterus associated with abnormal growth of cells of the myometrium or endometrium, and support the view that FP receptor antagonists are useful in treating such conditions.

Applicants note that in the sentence spanning pages 5 and 6 of the office action, the PTO asserts that "[t]*here is no evidence in the prior art that agents that prevent PGF2alpha having its effect on the FP receptor have any effects on patients with the above-described conditions, so the result of examples 2, 5 and 8 are unpredictable.*" Applicants agree that there has been no disclosure in the prior art that FP receptor antagonists can be used to treat pathological conditions of the uterus associated with abnormal growth of cells

of the myometrium or endometrium. That is precisely why the invention is novel and non-obvious.

However, this does not mean that there is undue burden in carrying out the invention. For the reasons given above, applicants submit that persons of skill in the art would be fully able to use FP receptor antagonists to treat the pathological conditions of the uterus in the manner claimed.

For all these reasons, the rejection of claims 1-9, 12, and 13 as lacking enablement should be withdrawn.

The rejection of claims 14-18 under 35 U.S.C. § 112, second paragraph, for indefiniteness is rendered moot by the cancellation of these claims. This rejection should be withdrawn.

The rejection of claims 1, 6-9, 12, and 13 under 35 U.S.C. § 112, second paragraph, for indefiniteness of the language "pathological condition of the uterus" is overcome by the above amendments.

Claim 1 has been amended to define the pathological condition of the uterus as one "associated with abnormal growth of cells of the myometrium or endometrium." Applicants submit that this language is a clear and definite, because persons of skill in the art would readily understand which pathological conditions fall into this definition. Therefore, this rejection should be withdrawn.

The rejection of claims 1-9 and 12-18 under 35 U.S.C. § 112, second paragraph, for indefiniteness is rendered moot with respect to claims 14-18 and is otherwise respectfully traversed in view of the above amendments. This rejection should be withdrawn.

The rejection of claim 13 under 35 U.S.C. § 112, second paragraph, for indefiniteness is respectfully traversed in view of the above amendments. This rejection should be withdrawn.

The rejection of claims 1, 6-9, and 12-18 under 35 U.S.C. § 102(e) as being anticipated by Sharif is overcome by the above amendments. As noted above, the limitation of claim 2 (now cancelled) has been introduced into pending claim 1. Because Sharif fails to

teach or suggest treating a pathological condition of the uterus as claimed, the rejection should be withdrawn.

The rejection of claims 1, 6-9, 12, and 13 under 35 U.S.C. § 103(a) for obviousness over Chemtob in view of Sharif is overcome by the above amendments. As noted above, the limitation of claim 2 has been introduced into pending claim 1. Because the combination of Chemtob and Sharif fails to teach or suggest treatment of pathological conditions of the uterus as claimed, the rejection should be withdrawn.

Finally, applicants note that the PTO refused to consider references 15-20 and 40 as identified on the Information Disclosure Statement filed on August 25, 2005. Each of these references (in a foreign language) was presented with an English language abstract that summarizes the content thereof. Therefore, applicants respectfully request consideration of these references and the return of a signed and initialed copy of the IDS that reflects consideration of references 15-20 and 40.

In view of all of the foregoing, applicants submit that this application is in condition for allowance and such allowance is respectfully requested.

Respectfully submitted,

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